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Application Serial Number	09/256,156
Filing Date	February 24, 1999
First Named Inventor	Gillies
Group Art Unit	1647
Examiner Name	R. B. Kapust
Attorney Docket No.	LEX-003
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	ENCLOSURES (check all that apply)									
Ø	Fee Transmittal Form		Copy of Notice t Parts of Applica	to File Missing ation (PTO-1553)		Appeal Communication to Board of Patent Appeals and Interferences				
	<ul><li>☐ Check Attached</li><li>☐ Copy of Fee</li><li>Transmittal Form</li></ul>		Formal Drawing	(s);		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)				
	Amendment/Response		and Accompany Convert to a Pro			Status Letter				
	☐ After Final		Application	]	$\boxtimes$	Return Receipt Postcard				
	Affidavits/declaration(s) Letter to Official Draftsperson		Power of Attorn (Revocation of I			Certificate of First Class Mailing under 37 C.F.R. 1.8				
	including Drawings [Total Sheets]		Terminal Discla	nimer		Additional Enclosure(s) (please identify below)				
	Extension of Time Request		Executed Declaration and Power of Attorney for Utility or Design Patent Application							
⊠	Second Supplemental Information Disclosure Statement		Small Entity Statement							
⊠	Form PTO-1449									
×	Copies of Second SIDS Citations (A55-94; B83- B105; C143-C235)		Request for Ref	fund						
	Certified Copy of Priority Document(s)		After Allowance to Group	ce Communication						
	Response to Missing Parts/ Incomplete Application									
CO	RRESPONDENCE ADDRESS			SIGNATURE BL	оск					
	ect all correspondence to: Patent A Testa, H	Thibeault, LLP			Respectfully submitted,					
	125 Hig Boston, Tel. No.	reet Towe gh Street , MA 021 .: (617) 24 .: (617) 24	Reg. No. 48,645 Tel. No.: (617) 248 Fax No.: (617) 248		8-7697	Brian A. Fairchild, Ph.D. Attorney for Applicant(s) Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110				



	Complete if Known
Application Serial Number	09/256,156
Filing Date	February 24, 1999
First Named Inventor	Gillies
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Examiner Name	R. B. Kapust
Attorney Docket No.	LEX-003

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METHOD OF PAYMENT		FEE	CALCULATION (continued)		
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to Deposit Account No. 20-0531.			G. J Jan. Gling for an oath		
Required Fees (copy of this sheet enclosed).	130	65	Surcharge - late filing fee or oath		
Additional fee required under 37 CFR 1.16 and	50	25	Surcharge - late provisional filing fee		
1.17.			or cover sheet		
Overpayment Credit.	130	130	Non-English specification		
	2,520	2,520	Request for ex parte reexamination		
3. Applicant claims small entity status.  FEE CALCULATION	110	55	Extension for reply within first month		
	420	210	Extension for reply within second		
1. FILING FEE	420	210	month		
	950	475	Extension for reply within third month		
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770 Utility filing fee	330	165	Notice of Appeal		
340 Design filing fee	330	165	Filing a brief in support of an appeal		
160 Provisional filing fee	290	145	Request for oral hearing		
	130	130	Petitions to the Commissioner	100.00	
	180	180	Submission of Information Disclosure	180.00	
Number Number Rate Amount			Statement		
Filed Extra	770	385	Filing a submission after final		
			rejection (37 CFR 1.129(a))		
Total Claims - 20 = x \$ 18.00 =	770	385	For each additional invention to be		
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CORRESPONDENCE ADDRESS	SIGNATURE BLOCK				
Direct all correspondence to:			Respectfully submitted		
Patent Administrator			1 2		
Testa, Hurwitz & Thibeault, LLP	Date: March		my month	_	
	Reg. No.: 4	8,645	Brian A. Fairchild, Ph.D.		
High Street Tower-125 High Street	Tel. No.: (6		97 Attorney for the Applicants		
Boston, MA 02110	Fax No.: (6			LLP	
Tel. No.: (617) 248-7000		,	High Street Tower-125 High		
Fax No.: (617) 248-7100			Boston, MA 02110	-	
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Gillies et al.

SERIAL NO.:

09/256,156

**GROUP NO.:** 

1647

FILING DATE:

February 24, 1999

**EXAMINER:** 

R. B. Kapust

TITLE:

Enhancing the Circulating Half-Life of Antibody-Based Fusion Proteins

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

# SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

### REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

	(1)	within three (3) months of the <b>filing date</b> of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the <b>date of entry of the national stage</b> as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the <b>first Office action</b> on the merits, or before the mailing of a <b>first Office action</b> after the filing of a request for continued examination under 37 C.F.R. 1.114; or
$\boxtimes$	(2)	after the period defined in (1) but before the mailing date of a <b>final action</b> or a <b>notice</b> of allowance under 37 C.F.R. 1.311, and
		the requisite Statement is below, OR
	$\boxtimes$	the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or

03/11/2004 EAREGAY1 00000051 09256156

Second Supplemental Information Disclosure Statement
Serial No. 09/256,156
Page 2 of 2

(3) after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND

the requisite Statement is below, AND

the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no additional fee is required for entry and consideration of this paper. If an

additional fee is required, please charge Deposit Account 20-0531.

Date: March 9, 2004 Reg. No. 48,645

Tel. No.: (617) 248-7697 Fax No.: (617) 248-7100

3030529

Respectfully submitted,

Brian A. Fairchild, Ph.D. Attorney for Applicant(s)

Testa, Hurwitz, & Thibeault, LLP

High Street Tower 125 High Street

Boston, Massachusetts 02110

FORM	PTO -	1449
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

FILING DATE: February 24, 1999 GROUP: 1647

E.			U.S. PATE	ENT DOCUMENTS			
EXAMS TRA	DEMAG	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A55	4,703,008	10/27/87	Lin			
	A56	5,019,368	5/28/91	Epstein et al.			
/	A57	5,441,868	8/15/95	Lin			
	-A58	5,457,038	10/10/95	Trinchieri et al.			
/	A59	5,547,933	8/20/96	Lin			
4	A60	5,618,698	4/8/97	Lin			
_/	-A61	5,645,835	7/8/97	Fell, Jr. et al.			
	A62	5,688,679	11/18/97	Powell			
	A63	5,756,349	5/26/98	Lin			
/	A64	5,807,715	9/15/98	Morrison et al.			
	A65	5,856,298	1/5/99	Strickland			
	A66	5,888,772	3/30/99	Okasinski et al.			
~	A67	5,922,685	7/13/99	Rakhmilevich et al.			
/	A68	5,955,422	9/21/99	Lin			
	A69	6,231,536	5/15/01	Lentz			
/	A70	6,284,536	9/4/01	Morrison et al.			
	A71	6,335,176	1/1/02	Inglese et al.			
	A72	6,340,742	1/22/02	Burg et al.			
	A73	6,348,192	2/19/02	Chan et al.			
	A74	6,444,792	9/3/02	Gray et al.			
/	A75	6,475,717	11/5/02	Enssle et al.			
	A76	6,485,726	11/26/02	Blumberg et al.			
	A77	6,506,405	1/14/03	Desai et al.			
	A78	6,583,272	6/24/03	Bailon			
	A79	6,586,398	7/1/03	Kinstler et al.			
	A80	6,617,135	9/9/03	Gillies et al.			
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	A81	2001/0053539	12/20/01	Lauffer et al.				
	A82	2002/0081664	6/27/02	Lo et al.				
-	A83	2002/0142374	10/3/02	Gallo et al.				
	A84	2002/0147311	10/10/02	Gillies et al.				
1	A85	2002/0192222	12/19/02	Blumberg et al.				
	A86	2002/0193570	12/19/02	Gillies et al.				
. /	A87	2003/0003529	1/2/03	Bayer				
	A88	2003/0044423	3/6/03	Gillies et al.				
	A89	2003/0049227	3/13/03	Gillies et al.				
	A90	2003/0105294	6/5/03	Gillies et al.				
	A91	2003/0012789	1/6/03	Blumberg et al.				
-	A92	2003/0157054	8/21/03	Gillies et al.				
/	A93	2003/0166163	9/4/03	Gillies				
	A94	2003/0166877	9/4/03	Gillies et al.				

## FOREIGN PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
/	B83	0 318 554 B1	6/7/89	EP					Y
	B84	0 640 619 A1	3/1/95	EP					Y
	B85	0 668 353 A1	8/23/95	EP					Y
	B86	1 088 888 A1	4/4/01	EP					Y
	B87	WO 94/24160	10/27/94	PCT					Y
	B88	WO 94/25055	11/10/94	PCT	-				Y
1	B89	WO 99/60128	11/25/99	PCT					Y
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SECOND SUPPLEMENTAL INFORMATION & DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

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	B92 WO 00/68376 11/16/00 PCT Y										
<del>-/</del>	B93 WO 00/78334 12/28/00 PCT Y										
/	B94	WO 01/10912	2/15/01	PCT					Y		
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1	B96	WO 01/58957	8/16/01	PCT							
J	B97	WO 02/02143	1/10/02	PCT							
1	B98	WO 02/066514	8/29/02	PCT					Y		
	B99	WO 02/072605	9/19/02	PCT							
/	B100	WO 02/079232	10/10/02	PCT							
/	B101 WO 02/079415 10/10/02 PCT										
/	B102 WO 02/090566 11/14/02 PCT										
/	B103 WO 03/015697 2/27/03 PCT Y							Y			
/	B104	WO 03/048334	6/12/03	PCT							
/	B105 WO 03/077834 9/25/03 PCT Y										
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)										
J	C143 Afonso et al., (1994), "The Adjuvant Effect of Interleukin-12 in a Vaccine Against Leishmania Major,"  Science, 263:235-237.										
	C144 Angal et al., (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," Molecular Immunology, 30(1):105-108.										
/	C145 Becker et al., (1996), "An Antibody-Interleukin 2 Fusion Protein Overcomes Tumor Heterogeneity by Induction of a Cellular Immune Response," Proc. Natl. Acad. Sci., 93:7826-7831.										
	C146 Becker et al., (1996), "Long-lived and Transferable Tumor Immunity in Mice after Targeted Interleukin-2 Therapy," J Clin Invest., 98(12):2801-2804.										
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/	C148 Bissery et al., (1997), "The Taxoids," in Cancer Therapeutics: Experimental and Clinical Agents, Teicher, ed., 175-193.										

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

FILING DATE: February 24, 1999 GROUP: 1647

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			FRUMEN PATEN	T DOCUMENTS							
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE				
1	C149	Bitonti et al., (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," Respiratory Drug Delivery, 8:309-312.									
/	C150	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships: Mutant Proteins that Test a Model of Tertiary Structure," The Journal of Biological Chemistry, 268(21):15983-15993.									
/	C151	Briggs et al., (1974), "Hepatic Clearance of Intact and desialylated Erythropoietin," <u>American Journal of Physiology</u> , 227(6):1385-1388.									
	C152	Buchli et al., (1993), "Structural and Biologic Properties of a Human Aspartic Acid-126 Interleukin-2 Analog," Archives of Biochemistry and Biophysics, 307(2):411-415.									
	C153		Caton et al., (1986), "Structural and Functional Implications of a Restricted Antibody Response to a Defined Antigenic Region on the Influenza Virus Hhemagglutinin," The EMBO Journal, 5(7):1577-1587.								
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/	C155	Chuang et al., (1993), "Effect of New Investigational Drug Taxol on Oncolytic Activity and Stimulation of Human Lymphocytes," Gynecol. Oncol., 49:291-298.									
	C156	Chuang et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the Anticancer Drug Taxol," Cancer Research, 54:1286-1291.									
	C157	Collins et al., (1988), "Identification of Specific Residues of Human Interleukin 2 that Affect Binding to the 70-kDa Subunit (p70) of the Interleukin 2 Receptor," <u>Proc. Natl. Acad. Sci. USA</u> , 85:7709-7713.									
	C158	Cruse et al., (1995), Illustrated Dictionary of Immunology, CRC Press, NY, p.156-7.									
	C159	Darling et al., (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.									
	C160	Davis et al., (2003), "Immunocytokines: Amplification of Anti-cancer Immunity," <u>Cancer Immunol.</u> <u>Immunother.</u> , 52:297-308.									
	C161	Dolman et al., (1998), "Suppression of Human Prostate Carcinoma Metastases in Severe Combined Immunodeficient Mice by Interleukin 2 Immunocytokine Therapy," Clin Cancer Res., 4(10):2551-7.									
	C162	Duncan et al., (1988), "The Binding Site for C1q on IgG," Nature, 332:738-740.									
	C163	Egrie et al., (2001), "Development and Characterization of Novel Erythropoiesis Stimulating Protein (NESP)," Nephrol. Dial. Transplant., 16:3-13.									
	C164	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.									
1	C165	Fell et al., (1992), "Ch	imeric L6 Antitumo	r Antibody," <u>J. Biol. Ch</u> e	em., 267(12	2):15552-1	5558.				
EXAMIN	ER	-		DATE CONSIDE	RED						

DISCLOSURE STATEMENT

FORM PTO - 1449
SECOND SUPPLEMENTAL INFORMATION

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

FILING DATE: February 24, 1999 GROUP: 1647

			U.S. PATEN	NT DOCUMENTS							
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE				
	C166	Fibi et al., (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85(5):1229-1236.									
	C167	Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti GD2 Antibody 14.G2a Plus Interleukin-2 in Children with Refractory Neutroblastoma," <u>Cancer</u> , 80:317-33.									
1	C168	Gan et al., (1999), "Specific enzyme-linked Immunosorbent Assays for Quantitation of Antibody-cytokine Fusion Proteins," Clin. Diagn. Lab. Immunol., 6(2):236-42.									
	C169	Gillies et al., (1991), "Expression of Genetically Engineered Immunoconjugates of Lymphotoxin and a Chimeric Anti-ganglioside GD2 Antibody," <a href="https://example.com/Hybridoma."><u>Hybridoma.</u></a> , 10(3):347-56.									
	C170	Gillies et al., (2002), "Bi-functional Cytokine Fusion Proteins for Gene Therapy and Antibody-targeted Treatment of Cancer," Cancer Immunol. Immunother., 51(8):449-60.									
/	C171	Gillies et al., (2002), "Improved Circulating Half-life and eRfficacy of an Antibody-interleukin 2 Immunocytokine Based on Reduced Intracellular Proteolysis," Clin. Cancer Res., 8(1):210-6.									
/	C172	Greene et al., (1975), Neuronal Properties of Hybrid Neuroblastoma X Sympathetic Ganglion Cells," <u>Proc.</u> Natl. Acad. Sci. USA, 72(12):4923-4927.									
	C173	Griffon-Etienne et al., (1999), "Taxane-induced Apoptosis Decompresses Blood Vessels and Lowers Interstitial Fluid Pressure inSolid Tumors: Clinical Implications," <a href="Mailto:Cancer Research">Cancer Research</a> , 59:3776-3782.									
/	C174	Hammerling et al. (1996), "In Vitro Bioassay for Human Erythropoietin based on Proliferative Stimulation of an Erythroid Cell Line and Analysis of Carbohydrate-dependent Microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.									
	C175	Hank et al., (1996), "Activation of Human Effector Cells by a Tumor Reactive Recombinant Anti-ganglioside GD2 Interleukin-2 Fusion Protein (ch14.18-IL2)," Clin Cancer Res., 2(12):1951-9.									
	C176	Hank et al., (2003), "Determination of peak serum levels and immune response to the humanized antiganglioside antibody-interleukin-2 immunocytokine," Methods Mol. Med., 85:123-31.									
	C177	Haraguchi, (1994), "Isolation of GD3 Synthase Gene by Expression Cloning of GM3 α-2,8-sialyltrasnferase cDNA using anti-GD2 Monoclonal Antibody," <u>Proc. Natl. Acad. Sci. USA.</u> , 91(22):10455-9.									
	C178	Harris, (1995), "Processing of C-terminal lysine and arginine residues of proteins isolated from mammalian cell culture," <u>J. Chromatogr. A.</u> , 705:129-134.									
<i>i</i> /	C179	Hezareh et al, (2001), "Effector Function Activities of a Panel of Mutants of a Broadly Neutralizing Antibody against Human Immunodeficiency Virus Type 1," <u>J. Virol.</u> , 75(24):12161-8.									
	C180	Hornick et al, (1999), "Pretreatment with a monoclonal antibody/interleukin-2 fusion protein directed against DNA enhances the delivery of therapeutic molecules to solid tumors," Clin. Cancer Res., 5:51-60.									
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EXAMIN	ER			DATE CONSID	ERED						

### Sheet 6 of 9 ATTORNEY DOCKET NO.: LEX-003 **FORM PTO - 1449** SECOND SUPPLEMENTAL INFORMATION APPLICANT(S): Gillies et al. DISCLOSURE STATEMENT SERIAL NO.: 09/256,156 FILING DATE: February 24, 1999 GROUP: 1647 FALLE PATENT DOCUMENTS FILING DATE IF SUB NAME CLASS DATE DOCUMENT EXAM. APPROPRIATE **CLASS** NUMBER INIT. Idusogie et al., (2000), "Mapping of the C1q Binding Site on Rituxan, a Chimeric Antibody with a Human C182 IgG1 Fc," J. Immunol., 164(8):4178-4184. Imboden et al., (2001), "The Level of MHC Class I Expression on Murine Adenocarcinoma Can Change the C183 Antitumor Effector Mechanism of Immunocytokine Therapy," Cancer Res., 61(4):1500-7. Ju et al., (1987), "Structure-Function Analysis of Human Interleukin-2: Identification of Amino Acid Residues for Biological Activity," Journal of Biological Chemistry, 262(12):5723-5731. Kato et al., (1997), "Mechanism for the Nonlinear Pharmacokinetics of Erythropoietin in Rats," The Journal C185 of Pharmacology and Experimental Therapeutics, 283:520-527. Kato et al., (1998), "Pharmacokinetics of Erythopoietin in Genetically Anemic Mice," Drug Metabolism and C186 Disposition, 26:126-131. Kitamura et al. (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates C187 Dependently on GM-CSF, IL-3, or Erythropoietin," Journal of Cellular Physiology, 140:323-334. Kushner et al., (2001), "Phase II Trial of the Anti-GD2 Monoclonal-macrophage-colony-stimulating Factor C188 for Neuroblastoma," J. Clin. Oncol., 19:4189-94. Locatelli et al., (2001), "Darbepoetin alfa Amgen," Current Opinion in Investigational Drugs, 2:1097-1104. C189 Lode et al., (1997), "Targeted interleukin-2 Therapy for Spontaneous Neuroblastoma Metastases to Bone C190 Marrow," J Natl Cancer Inst., 89(21):1586-94. Lode et al., (1998), "Immunocytokines: A Promising Approach to Cancer Immunotherapy," Pharmacol. Ther., C191 80(3):277-292. Lode et al., (2000), "What to do with Targeted IL-2," Drugs Today, 36(5):321-36. C192 Lode et al., (2000), "Melanoma Immunotherapy by Targeted II-2 Depends on CD4(+) T-cell Help Mediated C193 by CD40/CD40L Interaction," J. Clin. Invest., 105(11):1623-30. Macdougall, (2002), "Optimizing the Use of Erythropoietic Agents-Pharmacokinetic and Pharmacodynamic C194 Considerations," Nephrol. Dial. Transplant., 17:66-70. Metelitsa et al., (2002), "Antidisialoganglioside/granulocyte Macrophage-colony-stimulating Factor Ffusion C195 Protein Facilitates Neutrophil Antibody-dependent Cellular Cytotoxicity and Depends on FcyRII (CD32) and Mac-1 (CD11b/CD18) for Enhanced Effector Cell Adhesion and Azurophil Granule Exocytosis," Blood,

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**EXAMINER** 

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

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	* MANHANIPATENT DOCUMENTS									
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/256,156

			PAT	ENT DOCUMEN	TS				
EXAM. INIT.		DOCUMENT NUMBER	DATE	FILING DAT	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
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